le 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-808]

Schedules of Controlled Substances: Placement of Serdexmethylphenidate in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the *Federal Register* on May 7, 2021, placing serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act**.**

DATES: Effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION: This final rule refers to the single entity, serdexmethylphenidate. The chloride salt of serdexmethylphenidate is chemically known as 3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl]carbonyl]oxy]methyl]pyridinium chloride. This rule maintains the placement of serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act (CSA), thereby facilitating the commercial distribution of AZSTARYS as a controlled substance.

Background and Legal Authority

Under the CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. Law 114-89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II- V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On March 2, 2021, DEA received notification that the United States Food and Drug Administration approved, on that same date, a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride (3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl]carbonyl]oxy]methyl]pyridinium chloride) and dexmethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. In addition, on that same date, HHS recommended that DEA place serdexmethylphenidate in schedule IV of the CSA. On May 7, 2021, DEA, pursuant to 21 U.S.C. 811(j), published an IFR to place serdexmethylphenidate (including its salts, isomers, and salts of isomers) in schedule IV. 86 FR 24487. The IFR provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before June 7, 2021. DEA did not receive any requests for hearing or waiver of hearing.

Comments Received

In response to the IFR, DEA received seven comments. The submissions were from individuals or anonymous commenters. Four of the seven commenters were in support of the IFR to place serdexmethylphenidate in schedule IV of the CSA and one commenter was opposed to the placement of serdexmethylphenidate in schedule IV of the CSA. Of the two remaining comments, one had no relevant content and the other was against the scheduling of drugs in general and did not specifically comment on serdexmethylphenidate. This latter commenter associated the scheduling of substances with the ''war on drugs,'' which according to the commenter ''has failed.'' No response is necessary for the former comment and the latter comment is outside the scope of this current scheduling action and, therefore, these comments will not be addressed.

Support of the Interim Final Rule

Four commenters supported controlling serdexmethylphenidate as a schedule IV controlled substance. These commenters indicated support for scheduling serdexmethylphenidate under the CSA due to its similarity to phentermine, a schedule IV substance. Three of the commenters also recommended monitoring serdexmethylphenidate for increased public health risk or undertaking more clinical research to determine its long-term effects, but did not specify who should perform this monitoring or research. One of these commenters expressed concern about the misuse, including overprescribing, and abuse of stimulant medications in general, and believes that additional prevention measures are needed besides just placing the drug in schedule IV.

DEA Response. DEA appreciates the support for this rulemaking. The requests for additional research or prevention measures suggested by the commenters are outside of DEA's purview. Therefore, DEA has no response to these requests.

Opposition to the Interim Final Rule

One commenter opposed the IFR to control serdexmethylphenidate as a schedule IV drug. The commenter's primary issue with the scheduling of serdexmethylphenidate was that, as a new drug, there was no documented evidence of abuse potential. While the commenter did not completely disagree with the placement of serdexmethylphenidate in schedule IV, the commenter suggested that DEA should "let scientists experiment with it first to determine if it has any beneficial use" or if serdexmethylphenidate is more effective for controlling Attention Deficit Hyperactivity Disorder compared to current drug treatments. Thus, the commenter thought DEA should only schedule serdexmethylphenidate if problems occur. The commenter also referred to ongoing clinical studies for use of this substance in the treatment of Stimulant Use Disorder and the potential for future expansion of its use.

DEA Response: Scheduling a drug does not preclude its use as a therapeutic medication. Substances are scheduled to protect the public health and safety. In addition, substances that are scheduled are subject to regulatory controls and administrative, civil, and criminal sanctions of the schedule that it is placed to allow an adequate supply of controlled substances while preventing those substances from being diverted for illicit purposes. Thus, pursuant to 21 U.S.C. 811(a), the CSA authorizes the Administrator of DEA, under authority delegated by the Attorney General, to control any drug or other substance if it is found that the drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b). As discussed in the IFR, after considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential based upon the available information and all relevant data, DEA concluded that serdexmethylphenidate warranted control in schedule IV of the CSA.

The commenter's reference to ongoing clinical studies investigating the usefulness of serdexmethylphenidate in stimulant use disorder and its future therapeutic

potential is not relevant. DEA continues to support through this final rule its scheduling determination, and adopts the IFR, without change.

Requirements for Handling Serdexmethylphenidate

As indicated above, serdexmethylphenidate has been a schedule IV controlled substance by virtue of an IFR issued by DEA in May 2021. Thus, this final rule does not alter the regulatory requirements applicable to handlers of serdexmethylphenidate that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Serdexmethylphenidate is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, serdexmethylphenidate, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle serdexmethylphenidate, and is not registered with DEA, must submit an application for registration and may not handle serdexmethylphenidate unless DEA approves that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle serdexmethylphenidate but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of serdexmethylphenidate or may

transfer all quantities of serdexmethylphenidate to a person registered with DEA in accordance with 21 CFR part 1317, in additional to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Serdexmethylphenidate is subject to schedule III-V security requirements for DEA registrants and it must be handled and stored in accordance with 21 CFR 1301.71-1301.77. Non-practitioners handling serdexmethylphenidate must also comply with the employee screening requirements of 21 CFR 1301.90-1301.93. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of serdexmethylphenidate must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of serdexmethylphenidate was required to keep an inventory of serdexmethylphenidate on hand, as of May 7, 2021, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for serdexmethylphenidate, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for serdexmethylphenidate, or products containing serdexmethylphenidate, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of

schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of serdexmethylphenidate may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food and Drug Cosmetic Act and the CSA.

9. *Importation and Exportation.* All importation and exportation of serdexmethylphenidate must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving serdexmethylphenidate not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the IFR that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is: (1) Approved by HHS) and (2) HHS recommends control in CSA schedule II-V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. DEA issued an IFR on May 7, 2021, and solicited public comments on that rule. Subsection (j) further states that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). DEA is now responding to the comments submitted by the public and issuing the final rule, in accordance with 21 U.S.C. 811(j).

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 21, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Accordingly, the interim final rule amending 21 CFR part 1308, which published on May 7, 2021 (86 FR 24487), is adopted as a final rule without change.

Scott Brinks
Federal Register Liaison Officer,
Drug Enforcement Administration

[FR Doc. 2022-13538 Filed: 6/23/2022 8:45 am; Publication Date: 6/24/2022]